NDA 17-612/S-031
NDA 17-802/S-018
NDA 18-668/S-030
NDA 18-782/S-023

Wyeth Ayerst Laboratories **APR 3 2000**
Attention: Jennifer W. Phillips, Pharm.D.
Director, Women's Health Care Products
World Wide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299 Dear Ms. Phillips:

Please refer to your supplemental new drug applications dated December 12, 1996, received December 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for

Lo/Ovral Tablets (noregestrel/ethinyl estradiol), NDA 17-6 12;
Lo/Ovral-28 Tablets (noregestrel/ethinyl estradiol), NDA 17-802;
Nordette-21 Tablets (levonorgetsrel/ethinyl estradiol), NDA 18-668; and
Nordette-28 Tablets (levonorgetsrel/ethinyl estradiol), NDA 18-782.

We acknowledge receipt of your submission dated March 21, 2000. Your submission of March 21, 2000 constituted a complete response to our July 31, 1997 action letter.

We also refer to our March 4, 1998 letter requesting the addition of a pediatric use statement. These supplemental new drug applications provide for the following changes to the label:

INDICATIONS and USAGE section

Updated Trussel Table to the 1998 table in the prescribing information, and include results with the contraceptive sponge and the female condom.

PRECAUTIONS section

Pediatric Use subsection

"Safety and efficacy of **Tradename** have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of this product before menarche is not indicated."

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted March 21,2000, patient package insert submitted March 21, 2000). Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you, of your commitment, to reinstate the language, regarding the contraceptive sponge, to the instruction portion of the patient labeling in the next printing.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mockup form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jennifer Mercier, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, M.D., M.P.H.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

TABLE:PERCENTAGE OF WOMEN EXPERIENCING AN UNINTENDED PREGNANCY DURING THE FIRST YEAR OF A CONTRACEPTIVE METHOD

Method	Perfect Use	Average Use
Levonorgestrel implants	0.05	0.05
Male sterilization	0.10	0.15
Female sterilization	0.50	0.50
Depo-Provera® (injectable progestogen)	0.30	0.30
Oral contraceptives		5
Combined	0.10	NA
Progestin only	0.50	NA
IUD		
Progesterone	1.50	2.00
Copper T 380A	0.60	0.80
Condom (male) without spermicide	3	14
(female) without spermicide	5	21
Cervical cap		
Never given birth	9	20
Given birth	26	40
Vaginal Sponge		
Never given birth	9	20
Given birth	20	40
Diaphragm with spermicidal cream or jelly	6	20
Spermicides alone (foam, creams, jellies, and vaginal suppositories)	6	26
Periodic abstinence (all methods)	1-9*	25
Withdrawal	4	19
No contraception (planned pregnancy)	85	85

NA -not available

*Depending on method (calender, ovulation symptothermal, post-ovulation

Adapted from Hatcher RA et al, *Contraceptive Technology: 17th Revised Edition.* NY,NY: Ardent Medi, Inc, 1998